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VIA ECF

July 29, 2021

The Honorable Julien Xavier Neals, U.S.D.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street
Newark, New Jersey 07102

[redacted]

Re: *Corcept Therapeutics, Inc. v. Teva Pharm. USA, Inc.*,
Civil Action No. 18-3632 (JXN)(LDW) (consolidated)

Dear Judge Neals:

This firm, together with Quinn Emanuel, represents Plaintiff Corcept Therapeutics, Inc. ("Corcept") in the above-captioned matter. Pursuant to L. Civ. R. 7.1(d)(6), Corcept respectfully requests leave to submit the following brief sur-reply to address certain misstatements and new arguments set forth in the lengthy "reply" brief submitted by Defendant Teva Pharmaceuticals USA, Inc. ("Teva") "in support of its cross-motion for summary judgment of non-infringement of the '214 patent." ECF No. 211.

Although Teva claims that it filed its reply to "(i) correct certain misstatements of law and fact in Corcept's opposition to Teva's cross-motion and (ii) respond to certain new arguments raised by Corcept," there are no "misstatements" of law or fact in Corcept's opposition. And Teva does not actually identify a single ***new*** argument raised by Corcept for the first time in opposition to the cross motion, either. Instead, Teva's reply largely retreads old ground, dedicating page upon page to interpretation of cases already discussed at length in the parties' briefing. Teva itself, however, includes certain misstatements and new arguments in its reply, which if left unchallenged, could leave the Court with an inaccurate and misleading record.

I. Teva mischaracterizes its label

Teva repeatedly mischaracterizes the contents of its label in its reply. For instance, Teva argues that its "label does not instruct that co-administration of mifepristone and strong CYP3A inhibitors is ever 'necessary' or 'required.'" Despite putting quotation marks around the words "necessary" and "required," Teva fails to meaningfully address that these exact words appear in its label. *See, e.g.*, ECF No. 198 at § IV(A). Teva further argues that its label "is silent on whether co-administration should even be considered (much less actually undertaken)," despite the repeated references to co-administration in the label. *See Id.*

Without getting into each instance of Teva mischaracterizing its label, the parties' dispute boils down to the following question: Does Teva's label as a whole, including the instructions and clinical data set forth therein, allow this Court to determine, as a matter of law, that Teva's package insert will instruct or encourage physicians to practice the claimed methods of treatment? Corcept has presented indisputable facts indicating that this question must be answered in the affirmative. Specifically, Teva cannot plausibly dispute that: (1) the label instructs healthcare providers to co-administer mifepristone and strong CYP3A inhibitors "when necessary" to do so; (2) the label contains only one set of dosage adjustments for physicians to follow when co-administering mifepristone and strong CYP3A inhibitors; and (3) those dosage adjustments are directly covered by the asserted claims of the '214 patent. These undisputed facts alone would be dispositive of the infringement issue. But Teva's label goes even further, as it also expressly instructs that the claimed dosage adjustments are "***required***" when co-administering mifepristone with strong CYP3A inhibitors, and provides the results of clinical studies undertaken by ***Corcept*** (that formed the basis of the asserted '214 patent) demonstrating that the claimed dosage adjustments are safe. As the authority cited in Corcept's briefing makes clear, this is not a close case; the Court can and should find intent to encourage infringement as a matter of law on these indisputable facts. *See, e.g.*, ECF No. 198 at §§ IV(A)-(B).

II. Teva mischaracterizes the case law

Corcept explained at length why Teva's reliance on *HZNP* is inapplicable to the facts here. *See* ECF No. 198 at § IV(C); ECF No. 209 at § II(A)(1). In response, Teva misstates *HZNP* in its reply, claiming that the Federal Circuit "rejected an identical argument to the one Corcept advances here." Specifically, Teva argues Corcept's infringement claims are foreclosed because the patentee in *HZNP* argued that the claimed methods in that case were "medically necessary." But Teva overlooks that in *HZNP*, this was attorney argument ***devoid of support in the label itself***; nothing in the *HZNP* ***label*** instructed that it would ever be medically necessary to apply any second substance to the patient's skin, let alone the claimed second substances. *See* 940 F.3d at 701 (explaining that HZNP's medical necessity argument was based upon a warning in the label that never used the words "necessary" or "required.").[1] Teva's label is materially different. *See, e.g.*, ECF No. 198 at § IV(A); ECF No. 209 at 15.

Corcept also explained that accused infringers such as Teva cannot escape inducement liability by characterizing their proposed labels as providing "if/then" instructions, citing by way of example *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). *See, e.g.*, ECF No. 209 at 16-17. Teva's only response to *Vanda* is

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[1] Instead, HZNP's attorneys argued that the following warning about "Sun Exposure" indicated the claimed methods may be "necessary": "Instruct patients to avoid exposure to natural or artificial sunlight on treated knee(s) because studies in animals indicated topical diclofenac treatment resulted in an earlier onset of ultraviolet light-induced skin tumors. The potential effects of diclofenac sodium topical solution on skin response to ultraviolet damage in humans are not known." 940 F.3d at 701 n.11.

both incorrect and irrelevant. Specifically, Teva argues that "[i]n *Vanda*, a physician administering iloperidone—to *either* a poor *or* non-poor metabolizer—according to the dosing instructions in the label would *always* infringe." Teva's argument is contradicted by the final step of the claimed method in *Vanda,* which expressly requires reducing the "risk of QTc prolongation" in a *poor metabolizer*. 887 F.3d at 1121. Therefore, because the last step of the *Vanda* method requires reducing a risk of an adverse event in a poor metabolizer, Teva's position that prescribing the drug to "*either* a poor *or* non-poor metabolizer … would *always* infringe" is wrong. In any event, Teva's argument is irrelevant: a drug label need not cause physicians to "always infringe" in order to induce infringement. Instead, as the Federal Circuit itself noted in *Vanda*, "[e]ven if not every practitioner will prescribe an infringing dose, that the target dose range 'instructs users to perform the patented method' is sufficient to 'provide evidence of [the defendant's] affirmative intent to induce infringement.'" *Id.* at 1132.

Teva further misstates that Judge Simandle "confronted and rejected" an argument "similar" to Corcept's position in *Otsuka Pharmaceutical Co. v. Torrent Pharmaceuticals Ltd., Inc.*, 99 F. Supp. 3d 461 (D.N.J. 2015). *Otsuka* was not similar at all, because it was a carve-out case—meaning, instructions related to the patented method were deliberately removed from the generic drug label at issue, thereby evidencing the generic company's lack of intent to induce infringement in that case. [redacted] If anything, the reasoning of *Otsuka* illustrates precisely *why* the Court here should find that Teva's label induces infringement. As Judge Simandle explained, there is a "rather significant difference between a warning and an instruction. A warning provides information regarding a potential risk, but stops short of prescribing a specific course of action. An instruction, on the other hand, specifically directs that a particular action, or series of actions be taken." 99 F. Supp. 3d at 493 (quotations and citation omitted). Teva's label, of course, does not simply warn regarding the potential risk of co-administering mifepristone with strong CYP3A inhibitors; it instead provides a specific course of action to safely address the risk—in the form of the dosage adjustments claimed by the '214 patent. Moreover, Teva's label expressly instructs that "when necessary" to co-administer mifepristone with strong CYP3A inhibitors, the claimed "dose adjustment" steps are "required." *See* ECF No. 198 at § IV(A); ECF No. 209 at 14-15. Thus, rather than "stop[ping] short of prescribing a specific course of action," Teva's label instead ***requires*** that a particular series of actions be taken action, and there is no dispute that those actions are covered by the asserted claims of the '214 patent. *Id.*

III. Teva interjects new arguments regarding Table 3 of its label

Finally, Teva makes a number of new arguments for the first time in its reply regarding the clinical data contained in Table 3 of its label. *See e.g.*, ECF No. 211 at 6 (Teva arguing that the data contained in Table 3 "do not encourage using the combination [of mifepristone and strong CYP3A inhibitors] to treat Cushing's patients"); *id.* (Teva disagreeing that "the inclusion of this clinical data indicates that 'the claimed methods are safe.'"). These arguments were neither set forth in Teva's Local Patent Rules contentions, nor in its expert reports, and thus they

need not be considered. *See, e.g.*, *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10-06108, 2012 WL 3133943, at *3 (D.N.J. July 30, 2012) (explaining that because "the Local Patent Rules emphasize '*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act,'" a litigant is not permitted to inject new arguments into the case absent a showing of good cause).

Nonetheless, Teva's arguments are easily dealt with. First, Teva's label sufficiently induces infringement even without the need to rely on the clinical data contained in Table 3. *See* ECF No. 198 at §§ IV(B). Thus, even if credited, Teva's new arguments do not provide a basis to deny Corcept's summary judgment motion. Second, Teva's arguments should not be credited because they rely on attorney argument that is inconsistent with the only evidence in the record. *See, e.g.*, *Sec. & Data Techs., Inc. v. Sch. Dist. of Philadelphia*, 145 F. Supp. 3d 454, 470 (E.D. Pa. 2015) (rejecting argument where defendant's "characterization of the summary judgment record is not accurate and ignores evidence."). Specifically, the parties do not dispute that the FDA only approved the addition of the pertinent data to the label ***after*** the clinical studies underlying the claimed methods were completed. *See* ECF No. 199 at ¶ 31. Teva's expert did not even consider Table 3 in forming his opinions in this case (*see, e.g.*, ECF No. 209 at 27-28), let alone express any opinion regarding the data therein, whereas Corcept's expert will testify at trial that the clinical data in the clinical pharmacology section of Teva's package insert, including Table 3, "indicate it is safe to co-administer 600 milligrams mifepristone in combination with a strong CYP3A inhibitor like ketoconazole," which will in turn encourage physicians to co-administer in the first place. ECF No. 209 at 28 n.6 (quoting Exhibit 3 at 125:16-126:16). Accordingly, although the Court need not rely on these data to determine that the instructions in Teva's label will encourage an infringing use, to the extent that the Court does consider the data, they only provide additional, uncontroverted evidence of Teva's intent to induce infringement.

Accordingly, none of the arguments raised in Teva's reply warrant denial of Corcept's motion for summary judgment. At a minimum, Teva's 11th-hour injection of these arguments warrants denial of ***Teva's cross motion***—which is dependent upon the position that ***nothing*** in the label encourages co-administration, not even the clinical data in Table 3—since Teva has now attempted to raise a factual dispute over whether that data would (1) indicate the claimed methods are safe and (2) encourage a physician to practice the methods in the first place. *See, e.g.*, *Farmers & Merchants Nat. Bank v. San Clemente Fin. Grp. Sec., Inc.*, 174 F.R.D. 572, 577-78 (D.N.J. 1997).

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

William C. Baton

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cc: Hon. Leda D. Wettre, U.S.M.J. (via ECF)
All counsel of record (via e-mail)